IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

STATE OF OKLAHOMA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 05-cv-329-GKF(SAJ)**
	)	
TYSON FOODS, INC., et al.,	)	
	)	
Defendants.	)	

STATE OF OKLAHOMA'S BENCH BRIEF REGARDING DEFENDANTS' ORAL MOTIONS TO EXCLUDE THE TESTIMONY OF VALERIE J. HARWOOD, PH.D., AND ROGER OLSEN, PH.D.

Plaintiff, the State of Oklahoma, ex rel. W.A. Drew Edmondson, in his capacity as Attorney General of the State of Oklahoma and Oklahoma Secretary of the Environment C. Miles Tolbert, in his capacity as the Trustee for Natural Resources for the State of Oklahoma ("the State"), hereby submits this response in opposition to Defendants' oral motions to exclude the testimony of Valerie J. Harwood, Ph.D., and Roger Olsen, Ph.D.

Both during and after Dr. Harwood's testimony, Defendants made a motion to exclude her testimony on the grounds that "no one has done this before – found this process."[1] Unofficial Transcript, at 733. After Dr. Olsen testified before this Court on February 21 and 22, 2008, Defendants similarly made an oral motion to exclude his testimony regarding the principal component analysis ("PCA") he conducted with respect to poultry waste on the grounds that "[i]t's a novel approach, not peer reviewed. No other scientist in the world has ever come to this conclusion regarding this chemical signature." Unofficial Transcript, at 1021. For the reasons set forth below, neither Dr. Harwood's nor Dr. Olsen's testimony should be excluded.

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[1] Mr. Jorgensen renewed this motion on Thursday, February 21, 2008, at the end of the day, but this argument was not captured by the court reporter retained by the parties to prepare daily transcripts.

I. Argument

As previously noted by this Court, in cases that are not tried to a jury, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) does not govern, but rather provides guidance as to the benchmark of scientific reliability. As noted by the Supreme Court, there are several considerations in determining whether scientific evidence is reliable. First, courts should look to see whether the theory or technique "can be (and has been) tested." *Id.* at 593. Second, courts can look to whether the theory or technique has been subjected to peer review and publication. *Id.* The Court, however, noted that "[t]he fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." *Id.* at 594. Third, the Court suggested that courts should consider the known or potential rate of error. *Id.* Finally, the Court stated that "'general acceptance' can have a bearing on the inquiry." *Id.* "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." *Id.* (citation omitted). The Court concluded by stating, "Vigorous cross-examination [and the] presentation of contrary evidence . . . are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* at 596. On remand, the Ninth Circuit *Daubert* Court noted that these principles set forth by the Supreme Court are "illustrative" and did not "deem each of them to be equally applicable (or applicable at all) in every case." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

A. Despite Defendants' Characterization of Polymerase Chain Reaction, It Is a Reliable and Accepted Method for Microbial Source Tracking

PCR is a well-established methodology used by environmental scientists, criminal courts, and hospitals. *See, e.g., U.S. v. Trala*, 386 F.3d 536, 541 (3d Cir. 2004) (holding that the district

court did not abuse its discretion in admitting into evidence the PCR/STR DNA typing utilized as it met the standards for reliability and admissibility set forth in Fed. R. Evid. 702 and *Daubert*); *Stills v. Dorsey*, 7 Fed. Ap. 856, 859 (10th Cir. 2001) (holding that the state's admission of PCR evidence was not contrary to federal law); *U.S. v. Hicks*, 103 F.3d 837, 846-47 (9th Cir. 1996) (noting – over 15 years ago – that the "novelty" of PCR forensic testing should not prevent the district court from exercising its sound discretion in admitting such evidence once a proper *Daubert* showing has been made); *U.S. v. Beasley*, 102 F.3d 1440 (8th Cir. 1996) (finding that "the reliability of the PCR method of DNA analysis is sufficiently well established to permit the courts of this circuit to take judicial notice of it in future cases").

Moreover, although the use of PCR analysis with respect to poultry waste has not been addressed by the courts, the PCR analysis of swine DNA[2] has been both examined and held to be valid. *See U.S. v. Boswell*, 270 F.3d 1200 (8th Cir. 2001). In *Boswell*, the defendant was under indictment for making false statements to the government with respect to blood samples of swine. DNA testing through PCR concluded that a second set of samples submitted by the defendant were not from the same animals. The Eight Circuit held that the district court was justified in permitting the admission of PCR test results of the swine DNA because the PCR process was approximately 10 years old (at the time), had undergone extensive testing, and was widely recognized by scientists and courts around the country for forensic purposes. *Id.* at 1205. The government's expert witness testified that although not exactly the same as testing for human DNA, "the testing methodology has the same basic components." *Id.* In response to the defendants' argument that no protocol was followed during the analysis, the court noted its previous holding that "any alleged

[2] PCR has also been utilized to determine that white-tailed deer do not serve a prominent role as a reservoir for *E. Coli* 0157:H7. *See* Dunn, et al., "Prevalence of *Escherichia coli* 0157:H7 in White-tailed Deer from Louisiana", Journal of Wildlife Diseases, 40(2), pp. 361-365 (2004).

deficiencies in the conduct of the PCR analysis must so alter the methodology as to make the test results inadmissible." *Id.*

Defendants' sole stated basis for moving to exclude Dr. Harwood's PCR testimony is that the methodology used by Dr. Harwood is "novel", cutting edge, and has not been the subject of peer review. Ironically, despite the criticisms of Dr. Harwood's work, Defendants' experts appear to acknowledge its validity when they agree with, at least in part, the conclusions—just not when the conclusions are contrary to the interests of Defendants. Specifically, Drs. Myoda and Samadpour state, "If contamination was occurring in the laboratory the reliability of all the test results are suspect **except the duck and goose positive samples which were verified to be correct**." *See* Samadpour and Myoda Decl., ¶22. Under the principles set forth in *Daubert*, "[t]he focus, of course, must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595. Defendants cannot argue that the PCR proves that the biomarker is valid and "verified to be correct" for duck and goose all the while arguing that the entire methodology is invalid and not within the bounds of good science. The marker either exists or it does not. Defendants cannot have it both ways. Whether it is specific as to poultry is a question of the conclusions derived from the PCR analysis, not from the methodology itself.

Defendants criticize Dr. Harwood's PCR analysis on the grounds that it is not peer-reviewed or third-party tested. *See* Samadpour and Myoda Decl., ¶ 24. It is important to note that it is not PCR that Drs. Samadpour and Myoda call into doubt, but only the specific application of PCR to create the "'poultry biomarker' MST method." *Id.* In the face of the overwhelming acceptance of and reliance upon the PCR methodology in laboratories and courts around the world, Defendants must draw this fine line in order to gain any ground at casting doubt upon Dr. Harwood's valid and reliable work. Although courts look toward whether a study or methodology

has been peer-reviewed or published, it is certainly not dispositive. *See Daubert*, 509 U.S. at 594. Importantly, while Dr. Harwood's work has not specifically been peer-reviewed, the use of PCR in the context of microbial source tracking has been.

As demonstrated by its widespread acceptance in criminal courts, *see supra*, PCR is a generally accepted methodology. Moreover, the EPA has accepted PCR analysis and has recommended guidelines for conducting PCR analysis in environmental samples, which was followed by Dr. Harwood and North Wind. *See QA/QC Guidance for Laboratories Performing PCR Analysis on Environmental Samples* (EPA 815-B-04-001) (located at http://www.epa.gov/microbes/qa_qc_pcr10_04.pdf). Moreover although Defendants question Dr. Harwood's use of PCR in this context, PCR has been used for microbial source tracking in the same way used by Dr. Harwood. For example, "[g]ene specific PCR methods have been developed for *E. coli* carried by humans (Oshiro et al., 1997), cattle and swine (Khatib et al., 2002; Khatib et al., 2003,)." Defendants' Exhibit 271 (EPA Microbial Source Tracking Guide Document (EPA/600/R-05/064), at 28 (2005)); *see also* Shanks et. al, "Basin-Wide Analysis of the Dynamics of Fecal Contamination and Fecal Source Identification in Tillamook Bay, Oregon," Applied and Environmental Microbiology, at 5537-5546 (cow manure)[3]. Even Defendants' expert Dr. Samadpour, has used PCR as a means for microbial source tracking. PCR in this context is not so novel as Defendants would have this Court to believe.

Moreover, the methodology utilized by Dr. Harwood and North Wind can be tested. Northwind and Dr. Harwood prepared a set of Standard Operating Procedures that explains exactly

[3] *See also* Bernhard et al., "A PCR assay to discriminate human and ruminant feces on the basis of host differences in *Bacteroides-Prevotella* genes encoding 16S rRNA", Appl. Environ. Microbiol., 66: 4571-4574 (2000); Field et al., "Molecular approaches to microbiological monitoring: fecal source detection", Environ. Mon. Assess., 81:313-326 (2003); Bonjoch et al., "Multiplex PCR with 16S rRNA gene-targeted primers of *Bifodobacterium* spp. to identify sources of fecal pollution", Appl. Environ. Microbiol., 70(5):2171-2175 (2004).

how the PCR analysis was conducted. Defendants had access to the samples used by Dr. Harwood in her analysis. If Defendants wanted to test whether Dr. Harwood's analysis was valid, Defendants can perform PCR analysis on those samples—and in reality, under the cloak of the consulting expert privilege, may have done so. This methodology is clearly capable of replication. Finally, as noted above, Defendants' own experts seem to endorse the methodology when it favors Defendants (ducks and geese), but refuse to recognize its validity when it is contra to Defendants' position (chickens and cows).

Although there is "novelty" with respect to PCR analysis of **poultry waste**, the methodology is sound and has been specifically applied to other sources of waste in the environment. Dr. Harwood employed valid and reliable principles and methodologies in her work with the poultry biomarker. This evidence is not only admissible, but compelling in that it shows that bacteria associated with poultry waste can be found in the land-applied fields, the edge of field water samples, the groundwater, the streams, and the surface waters of the IRW.

B. Principal Component Analysis is a Well-Established Technique Used by Environmental Scientists to Track Sources of Contamination.

Defendants also argue that this poultry signature is novel and not peer-reviewed. As with PCR analysis, PCA is a well-established and recognized technique used by many environmental scientists to track a wide variety of waste through the environment. There are dozens of peer-reviewed articles where the authors used PCA to identify sources of environmental contamination. *See, e.g.,* V. Simeonov, et al, "Environmetric Modeling and Interpretation of River Water Data", Analytical and Bioanalytical Chemistry, v. 374, n.5, pp. 898-905 (2002); G. Mihailov, et al., " Multivariate Statistical Assessment of the Pollution Sources Along the Stream of Kamchia River, Bulgaria", Water Science and Technology, Vol. 51, No. 11, pp. 37-43 (2005); Hartman, P., "Polychlorinated Biphenyls in Narragansett Bay Surface Sediments", Chemosphere , v. 57, N.1,

pp. 9-20 (October 2004); Phillips, C., "Interpretations of Contaminant Sources to San Pedro Shelf Sediments Using Molecular Markers and Principal Component Analysis", ACS Symposium Series, v. 671, pp. 242-260 (Oxford University Press 1997).

Again Defendants attempt to paint a divide between what is widely accepted (i.e., PCA in environmental contamination source tracking) and what is novel (i.e., the signature of poultry waste). However, as noted above, PCA in the context of identifying sources of environmental contamination is utilized throughout the scientific community. The methodology is reliable. The opinion that there is a poultry signature and that signature is found in litter, in land applied soils, in edge of field samples, in groundwater, and in surface water is grounded in that well accepted, reliable methodology.

In addition, the PCA conducted by Dr. Olsen can be tested by merely running a database. Defendants could have performed their own sampling, conducted their own laboratory analysis, and performed their own PCA as well. In addition, they have been provided with the parameters and a copy of Dr. Olsen's database. Instead of actually testing Dr. Olsen's PCA, Defendants seek to exclude it by casting doubt on the reliability of a generally accepted method on the grounds that "this" poultry waste signature has never been seen before. This logic defies common sense.

As with Dr. Harwood's PCR analysis, it is the conclusions, not the methodology that is what Defendants seek to avert. The Supreme Court expressly warned courts in *Daubert* that it is this type of attack that must fail. Dr. Olsen's PCA should not be excluded from evidence.

II. Conclusion

Although Defendants characterize their attack against PCR and PCA conducted by the State's experts as one of methodology, a careful review of the state of science reveals that Defendants are merely attacking their conclusions. Exclusion of this type of evidence is not what

the *Daubert* Court envisioned. To the contrary, it is this type of evidence—evidence based in sound scientific methodology—that must be considered by the Court. Morever, as this Court presides over this matter, this evidence need not be excluded but can merely be weighed as deemed appropriate by the Court. Based on the foregoing, the State respectfully requests that the Court deny Defendants' motion to exclude the testimony of Dr. Harwood regarding PCR analysis and the testimony of Dr. Olsen with respect to PCA of poultry waste.

Respectfully Submitted,

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